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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,922	11/24/2003	Markus Pompejus	BGI-132CPCN	5830
959	7590	12/04/2007	EXAMINER	
LAHIVE & COCKFIELD, LLP			ZARA, JANE J	
ONE POST OFFICE SQUARE			ART UNIT	
BOSTON, MA 02109-2127			PAPER NUMBER	
			1635	
			MAIL DATE	DELIVERY MODE
			12/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/721,922

Applicant(s)

POMPEJUS ET AL.

Examiner

Jane Zara

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3,9-17,25,26,28-34,36,37 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,9-17,25,26,28-34,36,37 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10-25-07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office action is in response to the communication filed 9-25-07.

Claims 3, 9-17, 25, 26, 28-34, 36, 37 and 39-42 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections/New Rejections Necessitated by Amendments**

Claims 3, 9-17, 25, 26, 28-34, 36, 37 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the Office action mailed 3-22-07 and for the reasons set forth below.

The claims are drawn to compositions and methods comprising isolated nucleic acid molecules comprising at least 90% identity with SEQ ID NO. 1, or obtained under stringent hybridization conditions as described in the claims, or which nucleic acid

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comprises disruptions or modifications, and which encodes a polypeptide having UDP-N-Acetylmuramate-Alanane-Ligase activity.

Applicant's arguments filed 9-25-07 have been fully considered but they are not persuasive. Applicant argues that adequate written description has been provided for the genus of nucleic acids claimed because the instant specification and the prior art teach techniques for designing sequences and assays for identifying all of the nucleic acid molecules encompassed by the genus claimed. Applicant also argues that the disclosed SEQ ID No. 1 is representative of the genus of sequences claimed, especially in view of the specification and the general knowledge in the art.

Contrary to Applicant's assertions, the disclosure of SEQ ID No. 1, and the generic teachings provided by the instant specification and the art of well known molecular biology, mutagenesis and cloning techniques do not provide for adequate written description of the broad genus of compounds claimed, comprising any nucleic acid molecules sharing at least 90% identity with SEQ ID NO. 1, or capable of hybridizing with SEQ ID NO. 1 under stringent hybridization conditions. A patent is not a fishing license. Written description requires possession of a representative number of species for the broad genus claimed at the time of filing, not a disclosure of methods for obtaining potential members of the genus claimed at a future time.

The specification fails to describe elements which are essential to various functions of the claimed genus. The specification does not place any limit on the number of nucleic acid or amino acid substitutions, deletions, insertions and/or additions that may be made within the genus claimed. The scope of the claims includes

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numerous structural variants, and a significant number structural differences between genus members is permitted. Concise structural features that could distinguish compounds from others outside of the genus, and which describe the common structural attributes identifying members of the genus are missing from the disclosure.

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, applicant was not possession of the claimed genus. For these reasons, the instant rejection is maintained.

Claims 12-17, 25, 26, 28-34 and 36, 37, 39, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the in vitro expression of SEQ ID No. 1 in an appropriate microbial host cell, does not reasonably provide enablement for transfecting host cells in vivo, nor for the in vivo expression of SEQ ID No. 1 for the reasons of record set forth in the Office action mailed 3-22-07 and for the reasons set forth below.

The claims are drawn to compositions and methods for the in vitro or in vivo production or modulation of production of fine chemicals from any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, and for host cells transfected or generated in vivo and in vitro with any isolated nucleic acid molecule comprising at least 90% activity with SEQ ID NO. 1, or which nucleic acid molecule is disrupted or modified.

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Applicant's arguments filed 9-25-07 have been fully considered but they are not persuasive. Applicant argues that since it was well known in the art that UDP-N-Acetylmuramate-Alanine-Ligase performs an essential function in cell wall biogenesis by catalyzing one of the initial steps in peptidoglycan synthesis, and that modulation of expression of proteins that are involved in cell wall construction can affect the yield, production and/or efficiency of production of fine chemicals in a host cell, one skilled in the art would therefore appreciate that modulation of the activity or expression of this Ligase can serve to modulate (e.g. enhance) the production of fine chemicals.

Applicant is correct that the relationship between the instantly claimed Ligase, bacterial cell wall construction, and the subsequent yield of fine chemicals has been established in the art and in the instant specification. But, contrary to Applicant's assertions, this relationship does not provide full enablement for the ability to transfect host cells in an organism with SEQ ID NO. 1, or which nucleic acid comprises any disruptions or modifications. The instant specification is enabled for the in vitro transfection, in an appropriate host cell (microbial host cell). But the instant specification is not enabled for in vivo transfection of a host cell, and further whereby the production of fine chemicals in a host cell in vivo are modulated. Nor is it enabled for the transfection of host cells in vitro or in vivo of any modified or disrupted forms of SEQ ID NO. 1.

Applicants have not provided guidance in the specification toward methods of producing fine chemicals comprising the transfection of host cells in a subject with the compositions claimed, <sup>Nor</sup> ~~nor~~ for the modulation of production of fine chemicals in a host

cell in vitro comprising the transfection of any disrupted or modified forms of SEQ ID NO. 1.

The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of the ability to modulate production of fine chemicals in a host cell in an organism, whereby modulation of producing fine chemicals is obtained in that subject.

Since the specification fails to provide any particular guidance for the successful production of any fine chemicals, or modulation of production of any fine chemicals in a transfected host cell in a subject, and since determination of the factors required for accomplishing such production or modulated production is highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

For these reasons, the instant rejection, for lacking enablement over the in vivo scope claimed, is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara**  
**11-29-07**

*J Zara*  
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JANE ZARA, PH.D.  
PRIMARY EXAMINER